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Attention: TSCA Section 8(e) Coordinator

RE: Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) Chromosome Aberration Test

Dear Sir or Madam:

The Specialty Acrylates and Methacrylates (SAM) Panel (Panel) of the American Chemistry Council submits this letter on behalf of SAM Panel members¹ pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) to inform EPA of results of an Organization for Economic Cooperation and Development (OECD) Guideline 473 study titled “Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes.” In this *in vitro* study, TMPTA yielded positive results. This screening study was conducted as part of the Panel’s commitment to voluntarily provide information via the International Council of Chemical Associations (ICCA) to the OECD Screening Information Data Sets (SIDS) High Production Volume (HPV) chemical program.

The Panel is reporting these data on behalf of its members who manufacture, process or import TMPTA. Because of the uncertain relevance of *in vitro* genotoxicity tests in acrylate compounds, we express no views at this time concerning the relevance of these data for human risk assessment.

Unverified currently available results of the chromosome aberration test are enclosed. The final report is not yet available, but will be forwarded when received from the laboratory.



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¹ SAM Panel members are Arkema Inc.; BASF; Ciba Specialty Chemicals; Cognis; Mitsubishi Gas Chemical America, Inc.; Rhodia Inc.; Röhm GmbH & Co. KG; RohMax USA, LP; San Esters Corp.; Sartomer Company, Inc.; and UCB Surface Specialties, Inc.



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Page 2

If you have any questions, please contact me at (703) 741-5630 or via email at
anne_lehuray@americanchemistry.com.

Sincerely yours,



Anne P. LeHuray, Ph.D.
Manager, Specialty Acrylates &
Methacrylates Panel

Attachment:
cc: SAM Panel members

Unverified Results of OECD Guideline 473 study titled “Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes”

28205 MLH

Table 1: First experiment without S9 mix: cytotoxicity (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide Nb.	Mitotic index (%)	Mean	% of the control
0	49 M	7.2	5.45	100
	66 F	3.7		
0.78	54 M	8.1	6.10	112
	74 F	4.1		
1.56	73 M	5.2	5.05	93
	43 F	4.9		
3.13	64 M	5.8	5.45	100
	78 F	5.1		
6.25	50 M	5.6	4.45	82
	57 F	3.3		
12.5	75 M	2.8	3.00	55
	81 F	3.2		
18.75	65 M	3.4	3.00	55
	70 F	2.6		
25	79 M	1.2	0.60	11
	52 F	0.0		
37.5	45 M	0.0	0.00	0
	83 F	0.0		
MMC 3 µg/mL	56 M	2.7	2.85	52
	61 F	3.0		

M: male

F: female

0: vehicle control (DMSO)

MMC: mitomycin C

Nb.: number

Unverified Results of OECD Guideline 473 study titled “Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes”

28205 MLH

Table 2: First experiment without S9 mix: chromosome aberration (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide	Nb. of cells scored	NA	Structural chromosome aberrations (type and number)									Cells with structural chromosome aberrations			
				G	Chromatid		Chromosome		MA	PU	Total	Total	Nb.	mean %	Nb.	mean %
					D	Exch	D	Exch								
0	49 M	100	0	1	1	0	0	0	0	0	4	3	2	2.0	1	1.5
	66 F	100	1	0	2	0	0	0	0	0			2			2
3.13	64 M	100	1	0	1	0	0	0	0	0	3	2	1	1.5	1	1.0
	78 F	100	1	1	1	0	0	0	0	0			2			1
6.25	50 M	100	0	0	0	0	1	0	0	0	7	6	1	3.0	1	2.5
	57 F	100	1	1	3	1	1	0	0	0			5			4
18.75	65 M	50	0	5	28	1	2	0	3	0	95	84	22	50.0	19	46.0
	70 F	50	1	6	40	6	1	0	3	0			28		27	***
MMC 3 µg/mL	56 M	50	0	1	39	9	2	0	5	0	100	99	27	54.0	27	54.0
	61 F	50	2	0	30	10	2	0	2	0			27		27	***

NA: numerical aberrations, G: gap, D: deletion, Exch: exchange, MA: multiple aberrations, PU: pulverization.

M: male

F: female

0: vehicle control (DMSO)

MMC: mitomycin C

Statistical analysis: X² test ***: p < 0.001 (performed only for cells with structural aberrations excluding gaps)

Nb.: number

Unverified Results of OECD Guideline 473 study titled "Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes"

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Table 3: Second experiment without S9 mix: cytotoxicity (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide Nb.	Mitotic index (%)	Mean	% of the control
0	101 M 85 F	5.3 5.9	5.60	100
3.13	111 M 98 F	7.4 7.5	7.45	133
6.25	90 M 109 F	3.5 8.3	5.90	105
9.38	104 M 117 F	6.9 4.2	5.55	99
12.5	92 M 112 F	3.3 4.7	4.00	71
18.75	108 M 87 F	3.4 4.9	4.15	74
28.13	100 M 106 F	1.9 0.0	0.95	17
MMC 3 µg/mL	89 M 97 F	2.3 3.0	2.65	47

M: male

F: female

0: vehicle control (DMSO)

MMC: mitomycin C

Nb.: number

Unverified Results of OECD Guideline 473 study titled "Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes"

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Table 4: Second experiment without S9 mix: chromosome aberration (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide	Nb. of cells scored	NA	Structural chromosome aberrations (type and number)								Cells with structural chromosome aberrations				
				G	Chromatid		Chromosome		MA	PU	Total	Total	Nb.	mean %	Nb.	mean %
					D	Exch	D	Exch								
0	101 M	100	1	0	1	0	0	0	0	0	2	1	1	1.0	1	0.5
	85 F	100	0	1	0	0	0	0	0	0			1			0
9.38	104 M	100	0	0	5	0	0	0	0	0	15	15	5	6.0	5	6.0
	117 F	100	1	0	8	0	2	0	0	0			7		7	**
12.5	92 M	50	0	3	6	0	0	0	1	0	25	20	7	12.7	6	10.7
	112 F	100	0	2	8	2	1	0	2	0			12		10	***
18.75	108 M	50	1	1	16	2	2	0	3	0	60	53	14	32.0	13	30.0
	87 F	50	0	6	24	4	1	0	1	0			18		17	***
MMC 3.0 µg/mL	89 M	50	0	3	27	8	6	0	2	0	98	94	29	57.0	29	57.0
	97 F	50	0	1	34	11	4	0	2	0			28		28	***

NA: numerical aberrations, G: gap, D: deletion, Exch: exchange, MA: multiple aberrations, PU: pulverization.

M: male

F: female

0: vehicle control (DMSO)

MMC: mitomycin C

Statistical analysis: X² test **: p<0.01 (performed only for cells with structural aberrations excluding gaps)

***: p < 0.001

Nb.: number

Unverified Results of OECD Guideline 473 study titled "Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes"

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Table 5: First experiment with S9 mix: cytotoxicity (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide Nb.	Mitotic index (%)	Mean	% of the control
0	58 M 47 F	5.5 6.5	6.00	100
1.56	82 M 69 F	4.7 5.1	4.90	82
3.13	67 M 53 F	4.4 4.3	4.35	73
6.25	48 M 63 F	6.2 4.1	5.15	86
12.5	59 M 71 F	4.7 5.7	5.20	87
18.75	44 M 77 F	7.2 4.9	6.05	101
25	84 M 51 F	4.0 3.7	3.85	64
37.5	76 M 80 F	2.9 2.9	2.90	48
50	60 M 55 F	5.4 2.1	3.75	63
CPA 12.5 µg/mL	68 M 72 F	3.3 3.7	3.50	58
CPA 25 µg/mL	46 M 62 F	3.9 2.3	3.10	52

M: male

F: female

0: vehicle control (DMSO)

CPA: cyclophosphamide

Nb.: number

Unverified Results of OECD Guideline 473 study titled “Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes”

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Table 6: First experiment with S9 mix: chromosome aberration (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide Nb.	Nb. of cells scored	NA	Structural chromosome aberrations (type and number)								Cells with structural chromosome aberrations				
				G	Chromatid		Chromosome		MA	PU	Total +G	Total -G	Nb. +G	mean % +G	Nb. -G	mean % -G
					D	Exch	D	Exch								
0	58 M	100	0	0	1	0	0	0	0	0	2	2	1	1.0	1	1.0
	47 F	100	1	0	1	0	0	0	0	0			1		1	
18.75	44 M	100	0	0	3	0	0	0	0	0	8	7	3	3.0	3	2.5
	77 F	100	0	1	4	0	0	0	0	0			3		2	
37.5	76 M	50	0	1	14	1	0	0	1	0	35	32	10	22.0	10	21.0
	80 F	50	0	2	16	0	0	0	0	0			12		11	***
50	60 M	50	0	8	44	4	0	0	6	0	119	108	27	54.0	27	53.0
	55 F	50	0	3	43	4	3	0	4	0			27		26	***
CPA	68 M	50	0	1	26	1	4	0	1	0	57	53	19	33.0	17	30.0
12.5 µg/mL	72 F	50	0	3	15	3	3	0	0	0			14		13	***

NA: numerical aberrations, G: gap, D: deletion, Exch: exchange, MA: multiple aberrations, PU: pulverization.

M: male

F: female

0: vehicle control (DMSO)

CPA: cyclophosphamide

Statistical analysis: X2 test ***: p < 0.001 (performed only for cells with structural aberrations excluding gaps)

Nb.: number

Unverified Results of OECD Guideline 473 study titled “Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes”

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Table 7: Second experiment with S9 mix: cytotoxicity (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide Nb.	Mitotic index (%)	Mean	% of the control
0	91 M 103 F	5.4 5.8	5.60	100
9.38	113 M 94 F	4.2 5.3	4.75	85
18.75	102 M 110 F	5.3 5.5	5.40	96
28.13	86 M 99 F	6.7 6.0	6.35	113
37.5	118 M 93 F	2.8 3.3	3.05	54
50	114 M 107 F	3.7 3.3	3.50	63
75	95 M 116 F	0.0 0.2	0.10	2
CPA 12.5 µg/mL	88 M 105 F	2.0 3.9	2.95	53
CPA 25 µg/mL	115 M 96 F	1.5 4.1	2.80	50

M: male

F: female

0: vehicle control (DMSO)

CPA: cyclophosphamide

Nb.: number

Unverified Results of OECD Guideline 473 study titled "Trimethylolpropane Triacrylate (TMPTA; CAS RN 15625-89-5) *in vitro* mammalian chromosome aberration test in cultured human lymphocytes"

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Table 8: Second experiment with S9 mix: chromosome aberration (3-hour treatment; 20-hour harvest)

Doses µg/mL	Slide Nb.	Nb. of cells scored	NA	Structural chromosome aberrations (type and number)								Cells with structural chromosome aberrations				
				G	Chromatid		Chromosome		MA	PU	Total	Total	Nb. +G	mean % +G	Nb. -G	mean % -G
					D	Exch	D	Exch								
0	91 M	100	0	0	1	0	0	0	0	0	2	2	1	1.0	1	1.0
	103 F	100	0	0	1	0	0	0	0	0			1		1	
28.13	86 M	100	3	1	12	0	0	0	0	0	16	13	8	5.5	8	4.5
	99 F	100	0	2	1	0	0	0	0	0			3		1	
37.5	118 M	100	0	0	6	0	0	0	0	0	8	6	3	2.5	3	1.5
	93 F	100	2	2	0	0	0	0	0	0			2		0	
50	114 M	50	0	5	14	1	0	0	1	0	34	29	16	23.0	12	19.0
	107 F	50	1	0	11	0	2	0	0	0			7		7	***
CPA	88 M	50	0	2	17	2	1	0	0	0	46	43	15	31.0	14	30.0
12.5 µg/mL	105 F	50	1	1	20	1	1	0	1	0			16		16	***

NA: numerical aberrations, G: gap, D: deletion, Exch: exchange, MA: multiple aberrations, PU: pulverization.

M: male

F: female

0: vehicle control (DMSO)

CPA: cyclophosphamide

Statistical analysis: X2 test ***: p < 0.001 (performed only for cells with structural aberrations excluding gaps)

Nb.: number